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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/575,838	10/16/2006	Claudine Elvire Marie Bruck	VB60528	2078

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SMITHKLINE BEECHAM CORPORATION
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EXAMINER

MERTZ, PREMA MARIA

ART UNIT	PAPER NUMBER
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1646

NOTIFICATION DATE	DELIVERY MODE
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11/05/2008

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

US_cipkop@gsk.com

Office Action Summary	Application No. 10/575,838	Applicant(s) BRUCK ET AL.	
	Examiner Prema M. Mertz	Art Unit 1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11 August 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-19, 21-24, 26, 33 and 35-38 is/are pending in the application.
- 4a) Of the above claim(s) 1-9, 22-24, 26, 33 and 35-38 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 10-19 and 21 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>4/13/06</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

1. Applicant's election of Group 3 (claims 10-21, 25; species her-2-neu) in the reply filed on 8/11/08 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has *been* treated as an election without traverse (MPEP § 818.03(a)).

Claims 10-19 and 21 encompass the elected invention.

Claims 1-9, 22-24, 26, 33, 35-38, are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 8/11/08.

The recitation of "TSLP activity" in the election of species was a typographical error and the error is regretted by the Examiner.

Priority

2. Acknowledgment is made of applicant's claim for foreign priority under 35 U.S.C. 119(a)-(d). Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

Specification

3a. The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed. It is suggested that the title of the invention be amended to recite the kit claimed.

Art Unit: 1646

3b. New corrected drawings are required in this application because the drawings (Fig. 1A-B) contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 C.F.R. § 1.821 (a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 C.F.R. § 1.821-1.825 because the figures do not identify the sequences by a sequence identification number (SEQ ID NO). Full compliance with the sequence rules is required in response to this office action. The corrected drawings are required in reply to the Office action to avoid abandonment of the application. The requirement for corrected drawings will not be held in abeyance.

3c. There is no “Brief Description of the Drawings” before the Detailed Description on page 6 of the instant specification.

The following guidelines illustrate the preferred layout for the specification of a utility application. These guidelines are suggested for the applicant’s use.

Arrangement of the Specification

As provided in 37 CFR 1.77(b), the specification of a utility application should include the following sections in order. Each of the lettered items should appear in upper case, without underlining or bold type, as a section heading. If no text follows the section heading, the phrase “Not Applicable” should follow the section heading:

- (a) TITLE OF THE INVENTION.
- (b) CROSS-REFERENCE TO RELATED APPLICATIONS.
- (c) STATEMENT REGARDING FEDERALLY SPONSORED RESEARCH OR DEVELOPMENT.
- (d) THE NAMES OF THE PARTIES TO A JOINT RESEARCH AGREEMENT.
- (e) INCORPORATION-BY-REFERENCE OF MATERIAL SUBMITTED ON A COMPACT DISC.
- (f) BACKGROUND OF THE INVENTION.
 - (1) Field of the Invention.
 - (2) Description of Related Art including information disclosed under 37 CFR 1.97 and 1.98.
- (g) BRIEF SUMMARY OF THE INVENTION.

Art Unit: 1646

- (h) BRIEF DESCRIPTION OF THE SEVERAL VIEWS OF THE DRAWING(S).
- (i) DETAILED DESCRIPTION OF THE INVENTION.
- (j) CLAIM OR CLAIMS (commencing on a separate sheet).
- (k) ABSTRACT OF THE DISCLOSURE (commencing on a separate sheet).
- (l) SEQUENCE LISTING (See MPEP § 2424 and 37 CFR 1.821-1.825. A "Sequence Listing" is required on paper if the application discloses a nucleotide or amino acid sequence as defined in 37 CFR 1.821(a) and if the required "Sequence Listing" is not submitted as an electronic document on compact disc).

Claim Rejections - 35 USC § 112, first paragraph, written description

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4a. Claims 10-19, 21, are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims contain subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention.

The claims are drawn to a kit comprising (1) a pharmaceutical preparation of IL-18 polypeptide and (2) an immunogenic composition comprising an antigen and a saponin adjuvant.

The instant claims contemplate the use of a variant of IL-18 polypeptide. The instant specification teaches on page 23, lines 25-34, that variants may be used in which several, 5-10, 1-5, 1-3, 1-2 or 1 amino acids are substituted, deleted or added in any combination. Thus, the genus of IL-18 variants is very large and comprises species with different structures due to several 5-10, 1-5, 1-3, 1-2 or 1 amino acids substitutions or deletions and combination of

Art Unit: 1646

substitutions and deletions of that can be made to the IL-18 polypeptide sequence. The instant specification does not correlate the common structure of the numerous number of variants that can be made with the function of IL-18. The specification is devoid of any description (e.g. by common structure) of a representative number of species present in the genus of said variants. The disclosure of the murine and human IL-18 sequences is not representative of the plethora of variants that can be made and which function similarly to IL-18. The instant specification does not teach which several, 5-10, 1-5, 1-3, 1-2 or 1 amino acids and combinations of the 157 amino acids of IL-18 can be deleted or substituted in the amino acid sequence of the IL-18 polypeptide and still retain function. Furthermore, the instant claims contemplate the use of a derivative thereof of IL-18 polypeptide. The instant specification teaches that derivatives or variants include isolated polypeptides comprising an amino acid sequence which has at least 70% or 80% or 85% or 95% or 97-99% identity to SEQ ID NO: 6 or 7 (page 23, lines 13-18). SEQ ID NO: 6 and 7 are both 157 amino acids long and appear to be the mature bioactive IL-18. The instant specification does not teach the minimum sequence of SEQ ID NO: 6 or 7 necessary for its biological activity or function. The instant specification does not teach which amino acids e.g. which 30% or 20% or 15% or 5% or 3%-1% of SEQ ID NO: 6 or 7 can be changed and still maintain the function. Said derivatives or variants make up a large genus as any 30% or 20% or 15% or 5% or 3%-1% can be changed. The specification does not teach the common structure of said genus responsible for the function of the bioactive proteins. Absent sufficient description of the genus of said variants and derivatives one of skill in the art would not recognize that applicants had possession of said variants and derivatives contemplated in the instant invention.

Art Unit: 1646

Vas-cath Inc. v. Mahurkar, 19 USPQ2d 1111, clearly states that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention is, for purposes of the written description' inquiry, whatever is now claimed." (See page 1117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that (he or she) invented what is claimed." (See *Vas-Cath* at page 1116). As discussed above, the skilled artisan cannot envision the detailed chemical structure of the encompassed genus of polypeptides, and therefore conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the method of isolation. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method of isolating it. The compound itself is required. See *Fiers v. Revel*, 25 USPQ2d 1601 at 1606 (CAFC 1993) and *Amgen Inc. v. Chugai Pharmaceutical Co. Ltd.*, 18 USPQ2d 1016.

One cannot describe what one has not conceived. See *Fiddes v. Baird*, 30 USPQ2d 1481 at 1483. In *Fiddes*, claims directed to mammalian FGF'S were found to be unpatentable due to lack of written description for that broad class. The specification provided only the bovine sequence. Therefore, in the instantly claimed kit, only an IL-18 polypeptide of amino acid sequence set forth in SEQ ID NO:6 or 7 as recited in claim 15, but not the full breadth of the claims meets the written description provision of 35 U.S.C. 112, first paragraph. Applicant is reminded that *Vas-Cath* makes clear that the written description provision of 35 U.S.C. 112 is severable from its enablement provision (see page 1115).

Claim rejections-35 U.S.C. 112, second paragraph

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

Art Unit: 1646

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

Claims 14-15 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 14, line 2, is incorrect because it recites “from human or murine origin” rather than the correct “of human or murine origin”.

Claim 15 is rejected as vague and indefinite insofar as it depends on the above rejected claim for its limitations.

Claim Rejections - 35 USC 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Art Unit: 1646

6a. Claims 10-12, 14, 21, are rejected under 35 U.S.C. 103(a) as being unpatentable over Schwartz (US 6,562,798 B1, May 13, 2003 filed June 1, 1999) in view of the Stratagene catalog (1988, page 39).

Schwartz teaches a composition comprising a modified immunostimulatory sequence (ISS) comprising a CpG sequence (column 7 lines 41-60 i.e. CpG adjuvant), and a tumor antigen and immunogenic derivatives (tumor cell extracts, tumor protein subunits) (column 11 lines 13-40), and an adjuvant such as IL-18 (column 4, lines 59-61; column 11, lines 13-38, and 55-65; column 12 lines 15-24, and 41-61). Schwartz teaches that IL-18 acts as an immunomodulatory facilitator which supports and/or enhances the immunomodulatory activity of said modified immunostimulatory sequence (column 11 lines 54-67 to column 12 lines 1-24). Schwartz also teaches adjuvants which are squalene mixtures, saponin derivatives, oil-in-water emulsions and monophosphoryl lipid A (see column 12, lines 60-65). Schwartz also teaches that the composition comprising the adjuvants and antigen are injectable solutions (see column 21, lines 35-55; column 22, lines 4-10). The recitation of open-language "comprising" in the instant claims encompasses an ISS comprising a CpG sequence. However, the reference does not teach a kit comprising the composition.

The Stratagene catalog does teach a motivation to combine reagents of use into a kit (page 39, column 1). Stratagene states that "Each kit provides two services: (1) a variety of different regents have been assembled and premixed specifically for a defined set of experiments. Thus one need not purchase gram quantities of different reagents, each of which is needed in only microgram amounts, when beginning a series of experiments. When one considers all of the unused chemicals that typically accumulate in weighing rooms, desiccators,

Art Unit: 1646

and freezers, one quickly realizes that it is actually far more expensive for a small number of users to prepare most buffer solutions from the basic reagents. Stratagene provides only the quantities you will actually need, premixed and tested. In actuality, the kit format saves money and resources for everyone by dramatically reducing waste; (2) the other service provided in a kit is quality control” (page 39, column 1).

It would have been *prima facie* obvious to one having ordinary skill in the art at the time the invention was made to combine the components comprising (1) a pharmaceutical preparation of IL-18 polypeptide and (2) an immunogenic composition comprising an antigen and a saponin adjuvant as taught by Schwartz into a kit as taught by Stratagene since the Stratagene catalog teaches a motivation for combining reagents of use in any assay into a kit which provides convenience and ease of use to the customer/patient to be treated with the components of the kit.

6b. Claims 10-15, 21, are rejected under 35 U.S.C. 103(a) as being unpatentable over Schwartz et al (US 6,562,798 B1, May 13, 2003 filed June 1, 1999) in view of the Stratagene catalog (1988, page 39) as applied to claims 10-12, 14, 21 above and further in view of Cheever et al (US Patent No. 5,869,445) and Smithkline Beecham (WO 99/59565).

The teachings of Schwartz et al (US 6,562,798 B1, May 13, 2003 filed June 1, 1999) and the Stratagene catalog have been set forth above in paragraph 6a. However neither reference teaches her 2 neu as the tumor-associated antigen or IL-18 polypeptide consisting of the amino acid sequence set forth in SEQ ID NO:6 or 7.

Cheever et al teach a composition comprising an antigenic peptide of the tumor associated antigen her 2 neu which was administered to rats in a variety of adjuvants for

Art Unit: 1646

treatment of malignancies in which the her 2 neu oncogene is associated (see abstract; column 21, lines 55-64).

Smithkline Beecham teaches human and murine IL-18 polypeptides consisting of the amino acid sequence set forth in SEQ ID NO:6 and 7, respectively (see page 14, lines 23-30; SEQ ID NO:1 and SEQ ID NO:2 in reference).

It would have been *prima facie* obvious to one of ordinary skill in the art at the time the instant invention was made to include bioactive IL-18 polypeptide i.e. human or murine IL-18 as taught by Smithkline Beecham in the kit as taught by Schwartz and Stratagene because Schwartz teaches that IL-18 can be used as an adjuvant in a preparation comprising a tumor antigen, to support and/or enhance the immunomodulatory activity of said antigen and Smithkline Beecham teach bioactive IL-18 i.e. human IL-18 or murine IL-18 (the instant SEQ ID NO: 6 and SEQ ID NO: 7) which can be added to the composition of Schwartz with reasonable expectation of success.

It would also have been *prima facie* obvious to one having ordinary skill in the art at the time the invention was made to substitute her 2 neu as the antigen in the kit comprising a pharmaceutical composition comprising IL-18 polypeptide and composition comprising an antigen and a saponin adjuvant as taught by the combination of Schwartz and Stratagene because Schwartz teaches that IL-18 and saponin can be used as adjuvants in a preparation comprising a tumor antigen to support and/or enhance the immunomodulatory activity of the tumor antigen and Smithkline Beecham teaches bioactive IL-18 i.e. human or murine IL-18 which can be added to the composition of Cheever et al with reasonable expectation of success.

Art Unit: 1646

6c. Claims 10-12, 14, 16-19, 21, are rejected under 35 U.S.C. 103(a) as being unpatentable over Schwartz et al US 6,562,798 B1, May 13, 2003 filed June 1, 1999 in view of the Stratagene catalog (1988, page 39) as applied to claims 10-12, 14, 21 above and further in view of Prieels et al (US Patent No. 5,750,110).

The teachings of Schwartz et al (US 6,562,798 B1, May 13, 2003 filed June 1, 1999) and the Stratagene catalog have been set forth above in paragraph 6a. However neither reference teaches the specific saponin adjuvant QS-21 or monophosphoryl lipid A adjuvant 3D-MPL.

Prieels et al teach a composition comprising the adjuvants 3D-MPL and QS-21 which enhance immune responses to a given antigen (column 1, lines 4-27).

It would have been prima facie obvious to one of ordinary skill in the art at the time the instant invention was made to add the 3D MPL and QS-21 of Prieels et al to the kit comprising a composition as taught by Schwartz and Stratagene because Prieels et al teach adjuvants 3D-MPL and QS-21 which potentiate immune responses to an antigen. One of ordinary skill in the art would have been motivated to do so because Prieels teaches in column 1, lines 4-27, that the adjuvants 3D-MPL and QS-21 enhance immune responses to a given antigen and thus the artisan would have expected success using the adjuvants 3D-MPL and QS-21.

Claim rejections-Double Patenting

Non-statutory double patenting rejection (obviousness-type)

7. The non-statutory double patenting rejection, whether of the obviousness-type or non-obviousness-type, is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the

Art Unit: 1646

"right to exclude" granted by a patent. *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); and *In re Goodman*, 29 USPQ2d 2010 (Fed. Cir. 1993).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(b) and 8 may be used to overcome an actual or provisional rejection based on a non-statutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.78(d).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

7a. Claims 10-19, 21, are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 25-27 of copending Application No. 10/575,836 ('836 application). Although the conflicting claims are not identical, they are not patentably distinct from each other because claims 25-27 of application no. '836 (having all three common inventors with the instant application), claim a pharmaceutical kit comprising as active ingredients the following individual components: (1) an IL-18 polypeptide or bioactive fragment thereof; and (2) an immunogenic composition comprising an antigen or immunogenic derivative thereof and a CpG adjuvant, the active ingredients being for the simultaneous, separate or sequential use for the prophylaxis and/or treatment of a disease chosen from the group of: an infectious disease[s], a cancer, and an auto-immune disease[s].

Art Unit: 1646

Instant claims 10-19, 21, claim a kit comprising (1) a pharmaceutical preparation of IL-18 polypeptide and (2) an immunogenic composition comprising an antigen and a saponin adjuvant. Instant claims 10-19, 21, are genus of the claims in the '836 application and encompass subject matter to which the claims in the '836 application are a species because a kit for as recited in instant claims 10-19 and 21 encompasses claims 25-27 of the '836 application drawn to a kit for treatment of a disease. However, claims 25-27 of the '836 application are obvious from the instant claims because the claims in the '836 application are directed to specific embodiments encompassed by instant claims 10-19, 21. In addition, because of the open-language "comprising" in line 1 of claim 10 of the instant application, this limitation includes a CpG adjuvant as recited in the '836 application.

It would have been obvious to one of ordinary skill in the art at the time the instant invention was made that a kit comprising (1) a pharmaceutical preparation of IL-18 polypeptide and (2) an immunogenic composition comprising an antigen and a saponin adjuvant as recited in instant claims 10-19, 21 included a pharmaceutical kit comprising as active ingredients the following individual components: (1) an IL-18 polypeptide or bioactive fragment thereof; and (2) an immunogenic composition comprising an antigen or immunogenic derivative thereof and a CpG adjuvant, the active ingredients being for the simultaneous, separate or sequential use for the prophylaxis and/or treatment of a disease chosen from the group of: an infectious disease[s], a cancer, and an auto-immune disease[s] as recited in claims 25-27 of the '836 application. Therefore, the product in the '836 application is included in instant claims 10-19, 21.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Art Unit: 1646

Conclusion

No claim is allowed.

Claims 10-19, 21, are rejected.

Advisory Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Prema Mertz whose telephone number is (571) 272-0876. The examiner can normally be reached on Monday-Friday from 7:00AM to 3:30PM (Eastern time).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Nickol, can be reached on (571) 272-0835.

Official papers filed by fax should be directed to (571) 273-8300. Faxed draft or informal communications with the examiner should be directed to (571) 273-0876.

Information regarding the status of an application may be obtained from the Patent application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Prema Mertz/
Primary Examiner
Art Unit 1646

Application/Control Number: 10/575,838

Page 15

Art Unit: 1646